

Notice of Allowability

Application No.

09/700,817

Examiner

Richard Schnizer, Ph. D

Applicant(s)

TANIDA ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 1/9/04.
2. ☒ The allowed claim(s) is/are 1,3,4 and 6-18.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
 Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
 of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),
 Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with John Van Amsterdam on 4/2/04.

The application has been amended as follows:

IN THE CLAIMS:

In claim 1, delete "1:0.2-1:5" and insert --in the range of 1:0.2 to 1:5 (w/w)-- therefor.

In claim 3, delete "1:0.2:0.01-1:5:1" and insert --in the range of 1:0.2:0.01 to 1:5:1 (w/w)-- therefor.

Claim 8 (currently amended). The solid preparation for oral administration according to claim 4 wherein the disintegrator is mixed for [the] production in [the] a ratio in the range of 1:0.5 to 1:10 (w/w) against the content of the nucleic acid drug.

In claim 12, delete "disintegrators are" and insert --disintegrator is-- therefor.

13. (Currently amended) The solid preparation for oral administration according to claim 4 wherein the [saccharides are monosaccharides and/or disaccharides] saccharide is a monosaccharide or a disaccharide selected from the group consisting of lactose, fructose, sucrose, glucose xylitol, maltose, mannitol and sorbitol, or is a [polysaccharides and derivatives] polysaccharide or derivative thereof such as cellulose,

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crystalline cellulose, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, ethyl cellulose, starch, dextrin, dextran, pectin and pullulan.

In claim 14, delete "excipients are" and insert --excipient is—therefor.

In claim 15, delete "drugs are" and insert --drug is-- therefor.

In claim 16, delete "binders are" and insert --binder is--.

In claim 17, delete "carriers are" and insert --carrier is-- therefor.

In claim 18, delete "comprising" and insert --consisting of-- therefor.

Reasons for Allowance

Applicant's amendments overcome the previous rejections under 35 USC 112, second paragraph, 35 USC 102, and 35 USC 103. The previous rejection under 35 USC 112, first paragraph ~~for~~^{due} lack of enablement for compositions for delivery of phage or triplex forming nucleic acids to the lower digestive tracts is withdrawn for the following reasons. In the response filed 1/9/04, Applicant presented evidence that at the time of filing phage had been developed that were useful for delivering and expressing nucleic acids in animals in vivo. See Gold et al US Patent 5,736,388. In view of the fact that one could deliver other nucleic acids and viruses to the colon, a composition comprising such phage is be enabled. With respect to triplex forming oligonucleotides (TFOs), a further review of the prior art shows that prior to the time of filing, it was established that TFOs could affect gene expression in eukaryotic cells by binding to promoter regions of chromosomal genes. In view of the fact that antisense oligonucleotides can be delivered to the colon and will function to inhibit gene expression therein, the fact that


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the TFOs and antisense both function by hybridization to cellular target sequences, and in the absence of specific evidence showing that TFOs will not function in vivo, the rejection is withdrawn.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:20 AM and 3:50 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, John Leguyader, be reached at 571-272-0760. The official central fax number is 703-872-9306. Inquiries of a general nature or relating to the status of the application should be directed to the Patent Analyst Trina Turner whose telephone number is 571-272-0564.



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Richard Schnizer, Ph.D.